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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,892	08/20/2003	Michael C. Bednarek	11531US.01	8201

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EXAMINER

TOY, ALEX B

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 06/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/645,892

Applicant(s)

BEDNAREK, MICHAEL C.

Examiner

Alex B. Toy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 25 and 27-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 August 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/30/04; 2/3/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Invention I (claims 1-26) and Species I in the reply filed on May 15, 2006 is acknowledged. Claims 27-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. In addition, the examiner withdraws claim 25 as being drawn to nonelected Species VI shown in Fig. 11.

In summary, claims 25 and 27-31 are withdrawn from further consideration. Claims 1-24 and 26 are examined.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the electrode surface that is recessed below and alternatively raised above the level of the outer surface of the catheter shaft must be shown or the features canceled from the claims 15 and 17. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet,

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and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1, applicant claims that the electrode is interposed between the inner and outer surfaces. In claims 16 and 17, however, applicant claims that the electrode is flush or raised above the outer surface.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-11, 13, 15, 19-23, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bednarek (U.S. Pat. No. 6,120,500) in view of Swanson (U.S. Pat. No. 5,582,609).

Regarding claim 1, Bednarek discloses an ablation catheter comprising:

a catheter shaft defining an inner surface 20 and an outer surface 42 (Fig. 11);

at least one coiled electrode 46 interposed between the inner surface and the outer surface (Fig. 11); and

the outer tubular surface 42 defining at least one electrode aperture 38 such that a portion of the electrode is exposed (Fig. 11).

The claim differs from Bednarek in calling for the electrode to be a braided electrode. Swanson, however, teaches that a coil-type electrode alternatively can be made using braided wire (col. 7, ln. 55-61). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a braided electrode in the device of Bednarek in view of the teaching of Swanson as an obvious alternate way of making a coil-type electrode.

Regarding claim 2, Bednarek discloses the catheter of claim 1 in view of Swanson. In addition, Bednarek discloses a lumen 39 within the catheter shaft (Fig. 11).

Regarding claim 3, Bednarek discloses the catheter of claims 1 and 2 in view of Swanson. In addition, Bednarek discloses the inner surface 20 of the catheter shaft defining at least one fluid aperture providing a fluid flow path past the electrode (col. 10, ln. 25-30). Since Bednarek discloses that fluid is introduced through lumen 39 so that fluid can flow through the electrode 46, there inherently must be at least one fluid aperture in the inner surface 20 to allow the fluid to flow through the electrode.

Regarding claim 4, Bednarek discloses the catheter of claims 1-3 in view of Swanson. In addition, Bednarek discloses an introduction system in fluid communication with the lumen 39, the introduction system configured to provide a fluid material to the lumen (col. 10, ln. 25-30).

Regarding claim 5, Bednarek discloses the catheter of claims 1-4 in view of Swanson. In addition, Bednarek discloses that the lumen 39 is configured to guide the fluid media through the at least one fluid aperture (col. 10, ln. 25-30 and the rejection of claim 3).

Regarding claim 6, Bednarek discloses the catheter of claims 1-5 in view of Swanson. In addition, Bednarek discloses that the at least one fluid aperture is located so as to guide the fluid media past the braided electrode substantially to move blood away from the braided electrode to lessen formation of coagulum (col. 10, ln. 25-30 and col. 13, ln. 47-49). Since the fluid of Bednarek flows through the electrode in the same

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manner as disclosed by applicant, the location of the aperture inherently performs the claimed intended use.

Regarding claim 7, Bednarek discloses the catheter of claims 1-4 in view of Swanson. In addition, Bednarek discloses that the fluid media comprises a conductive fluid media (col. 4, ln. 6-10).

Regarding claim 8, Bednarek discloses the catheter of claims 1-4 and 7 in view of Swanson. In addition, Bednarek discloses that the conductive fluid media is configured to flow past the at least one braided electrode and conduct ablative energy to a target tissue (col. 4, ln. 6-10).

Regarding claims 9-11, Bednarek discloses the catheter of claims 1-4 and 7-8 in view of Swanson. In addition, ablation by ohmic energy, convection, and conduction is inherent to the device of Bednarek, since Bednarek uses an electrode with conductive fluid.

Regarding claim 13, Bednarek discloses the catheter of claim 1 in view of Swanson. In addition, Bednarek discloses that the electrode has a length of at least 0.4 cm (col. 10, ln. 20-21 and Fig. 11). Since 0.4 cm is a minimum length, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the electrode of Bednarek at least 1 cm as a matter of routine skill in the art that is in accordance with the parameters disclosed by Bednarek.

Regarding claim 15, Bednarek discloses the catheter of claim 1 in view of Swanson. In addition, Bednarek discloses that the at least one braided electrode 46

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generally defines an electrode surface that is recessed below the level of the outer surface 42 of the catheter shaft (Fig. 11).

Regarding claim 19, Bednarek discloses the catheter of claim 1 in view of Swanson. In addition, Bednarek discloses that the catheter shaft defines a second lumen 23 (Fig. 11).

Regarding claim 20, Bednarek discloses the catheter of claims 1 and 19 in view of Swanson. In addition, Bednarek discloses a control wire 16 connected with the catheter shaft and located within the second lumen.

Regarding claim 21, Bednarek discloses the catheter of claims 1, 19, and 20 in view of Swanson. In addition, Bednarek discloses that the control wire is precurved to manipulate the catheter shaft such that the catheter shaft forms a substantially circular shape (col. 8, ln. 7-40 and Fig. 2).

Regarding claim 22, Bednarek discloses the catheter of claims 1 and 19-21 in view of Swanson. In addition, Bednarek discloses that the substantially circular shape is adapted to conform to the inner shape of the pulmonary vein. The device of Bednarek is inherently adaptable to conform to the inner shape of the pulmonary vein.

Regarding claim 23, Bednarek discloses the catheter of claims 1 and 19 in view of Swanson. In addition, Bednarek discloses that the at least one braided electrode is connected with at least one corresponding wire adapted to connect with an ablation energy source (col. 9, ln. 67 – col. 10, ln. 5).

Regarding claim 26, Bednarek discloses an ablation catheter in view of Swanson comprising:

braided electrode means 46 for forming an ablation lesion through contact with a target tissue;

catheter shaft means 22 for locating the braided electrode means adjacent the target tissue;

and lumen means 39 for channeling a fluid media past the braided electrode means.

See Fig. 11 and the preceding rejection of claim 1.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bednarek (U.S. Pat. No. 6,120,500) in view of Swanson (U.S. Pat. No. 5,582,609) and further in view of Swartz (U.S. Pat. No. 6,080,151).

Regarding claim 24, Bednarek discloses the catheter of claims 1, 19, and 23 in view of Swanson. In addition, Bednarek discloses at least one separate lumen to accommodate the at least one wire for connecting the electrode to the ablation energy source (col. 9, ln. 67 – col. 10, ln. 5). Bednarek does not specify that the at least one wire is routed through the second lumen as claimed. Swartz, however, teaches routing the electrode wires through a second lumen 29 that also includes a control wire 24 in order to keep the wires separate from the fluid delivery lumen 18 (Figs. 2-3). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have routed the electrode wire of Bednarek through the second lumen with the control wire in view of the teaching of Swartz in order to keep the wires separate from the fluid delivery lumen.

Claims 12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bednarek (U.S. Pat. No. 6,120,500) in view of Swanson (U.S. Pat. No. 5,582,609) and further in view of Swartz (U.S. Pat. No. 6,080,151).

Regarding claim 12, Bednarek discloses the catheter of claim 1 in view of Swanson. The claim differs from Bednarek in calling for the at least one braided electrode aperture to have a length in the range of about 1 centimeter to about 10 centimeter. Swartz, however, discloses an analogous ablation catheter with electrode apertures 20 that he teaches can be of any size or shape that permit the passage of the conductive media through the lumen of the catheter without compromising the structural integrity of the catheter (col. 7, ln. 54-62 and Fig. 3). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the apertures of Bednarek have a length of at least 1 cm in view of the teaching of Swartz since Swartz teaches that it is obvious to vary the aperture size.

Regarding claim 14, Bednarek discloses the catheter of claim 1 in view of Swanson. The claim differs from Bednarek in calling for the at least one braided electrode aperture to have a width in the range of about 60 degrees to about 180 degrees. Again, Swartz, discloses an analogous ablation catheter with electrode apertures 20 that he teaches can be of any size or shape that permit the passage of the conductive media through the lumen of the catheter without compromising the structural integrity of the catheter (col. 7, ln. 54-62 and Fig. 3). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the apertures of Bednarek have a width in the range of about 60 degrees to about

180 degrees in view of the teaching of Swartz since Swartz teaches that it is obvious to vary the aperture size.

Claims 1 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over a second embodiment of Bednarek (U.S. Pat. No. 6,120,500) in view of Swanson (U.S. Pat. No. 5,582,609).

Regarding claim 1, in a second embodiment, Bednarek discloses an ablation catheter comprising:

a catheter shaft defining an inner surface 210 and an outer surface 14 (Fig. 11);
at least one ring electrode 37 interposed between the inner surface and the outer surface (col. 9, ln. 58-62 and Fig. 7); and
the outer tubular surface 14 defining at least one electrode aperture (the distal opening of 14) such that a portion of the electrode is exposed (Fig. 7).

The claim differs from Bednarek in calling for the electrode to be a braided electrode. Swanson, however, teaches using a braided electrode (col. 7, ln. 55-61). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a braided electrode in the device of Sun in view of the teaching of Swanson as an obvious alternate type of electrode that well-known in the art.

Regarding claim 16, Bednarek discloses the catheter of claim 1 in view of Swanson. In addition, Bednarek discloses that the placement of the electrodes may be adjusted by advancing or withdrawing the inner guiding introducer 12 in respect to the

outer guiding introducer 14 (col. 12, ln. 53-57 and Fig. 7). Therefore, the device of Bednarek is inherently capable of having at least one electrode 37 define an electrode surface that is generally flush with the outer surface 14 of the catheter shaft.

Regarding claim 17, Bednarek discloses the catheter of claim 1 in view of Swanson. In addition, Bednarek discloses that at least one electrode 37 defines an electrode surface that is raised above the outer surface 14 of the catheter shaft (Fig. 7).

Regarding claim 18, Bednarek discloses the catheter of claim 1 in view of Swanson. In addition, Bednarek discloses that the at least one electrode 37 is configured to at least partially contact the tissue during use (Fig. 7).

Claims 1 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun (WO 00/78239) in view of Swanson (U.S. Pat. No. 5,582,609).

Regarding claim 1, Sun discloses an ablation catheter comprising:
a catheter shaft defining an inner surface 22 and an outer surface 172 (Fig. 9c);
at least one electrode 46 interposed between the inner surface and the outer surface (pg. 33, ln. 11-21 and Fig. 9c); and

the outer tubular surface defining at least one electrode aperture such that a portion of the electrode is exposed (Fig. 9c).

The claim differs from Sun in calling for the electrode to be a braided electrode. Swanson, however, teaches using a braided electrode (col. 7, ln. 55-61). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was

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made to have used a braided electrode in the device of Sun in view of the teaching of Swanson as an obvious alternate type of electrode that well-known in the art.

Regarding claim 18, Sun discloses the catheter of claim 1 in view of Swanson. In addition, Sun discloses that the at least one braided electrode is configured to at least partially contact the tissue during use (Fig. 8c).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

US 4776334 A	USPAT	Prionas; Stavros D.
US 4860769 A	USPAT	Fogarty; Thomas J. et al.
US 5397304 A	USPAT	Truckai; Csaba
US 5411025 A	USPAT	Webster, Jr.; Wilton W.
US 5433708 A	USPAT	Nichols; Colin J. et al.
US 5826576 A	USPAT	West; Scott H.
US 5951471 A	USPAT	de la Rama; Alan et al.
US 6325797 B1	USPAT	Stewart; Mark T. et al.
US 20020026187 A1	US-PGPUB	Swanson, David K.
US 6391024 B1	USPAT	Sun; Weimin et al.
US 6692492 B2	USPAT	Simpson; John A. et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alex B. Toy whose telephone number is (571) 272-1953. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AT *AT*
5/26/06

Michael Peffley
MICHAEL PEFFLEY
PRIMARY EXAMINER